

III. REMARKS/ARGUMENTS

Claims 1-8 and 11-25 are pending. Claim 1 has been amended. Support for amended claim 1 can be found in the specification, e.g. at page 3, last line to page 4, line 16; and the examples.

A. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

In the Office Action, claim 17 was rejected on the grounds of having insufficient antecedent basis for the term “the weight ratio of hydrophobic fusible material to hydrophilic organic polymeric wicking agent.”

In response, claim 17 has been amended to depend from claim 4 in order to provide proper antecedent basis. Accordingly, the Examiner is respectfully requested to remove this rejection.

B. DOUBLE PATENTING REJECTION

In the Office Action, claims 1-8 and 11-15 were rejected under the judicially created doctrine of obviousness type double patenting over claims 1-8 and 11-22 of U.S. Patent No. 6,399,096 and over claims 1-33 of U.S. Patent No. 5,965,163.

It is respectfully submitted that the filing of terminal disclaimers will be considered upon indication that the pending claims are otherwise allowable.

C. REJECTION UNDER 35 U.S.C. § 102(b)

In the Office Action, claims 1-4, 8, 11, 12, 14-17 and 23-25 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,828,836 (hereinafter “the Elger patent”).

Although Applicants disagree with this rejection, independent claim 1 has been amended to recite, in pertinent part, “a solid, oral, controlled release pharmaceutical dosage form which comprises “an extrudate comprising a pharmaceutically active ingredient . . . dispersed in a matrix. . . , wherein said extrudate is directly incorporated into a capsule or tablet” in order to expedite the issuance of a patent. It is respectfully submitted that the Elger patent does not teach

or suggest that the formulations disclosed therein comprise an “extrudate” comprising the active agent dispersed in a matrix as presently claimed. Accordingly, it is respectfully submitted that independent claim 1 is not anticipated by the Elger patent.

Further, independent claim 11 recites, in pertinent part, “... (b) extruding the agglomerates whereby the extrudate is obtained as extruded pieces or an elongate extrudate is formed into pieces....” It is respectfully submitted that the Elger patent does not teach or suggest that the methods of preparing the formulations disclosed therein comprise an “extruding” step as recited in claim 11. Accordingly, it is respectfully submitted that independent claim 11 is not anticipated by the Elger patent.

In view of the above arguments, Applicants respectfully request that the Examiner remove the 102(b) rejection over claims 1-4, 8, 11, 12, 14-17 and 23-25.

D. REJECTION UNDER 35 U.S.C. § 103(a)

In the Office Action, claims 5 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Elger patent.

In response, it is noted that claims 5 and 17 depend on claims 1 and 11 respectively. As discussed above, the Elger patent does not teach or suggest the “extrudate” limitation recited in claim 1, or the “extruding” limitation in claim 11. Accordingly, it is respectfully submitted that claims 5 and 17 are not suggested by the Elger patent as they incorporate all of the limitations of claims 1 and 11, respectively.

In view of the above arguments, Applicants respectfully request that the Examiner remove the 103(a) rejection over claims 5 and 17.

E. **CONCLUSION**

In view of the arguments presented, Applicants respectfully submit that the pending claims are in condition for allowance. An early and favorable Action on the merits is earnestly solicited.

A check in the amount of \$110.00 is enclosed for the fee for a one month extension of time. If it is determined that any additional fees are due or that any fees have been overpaid, the Commissioner for Patents is hereby authorized to charge said fees or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,

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